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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/920,159 08/01/01 KATAKUSE

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THOMAS HOXIE

HM22/1029

NOVARTIS CORPORATION
PATENT AND TRADEMARK DEPT

564 MORRIS AVENUE
SUMMIT NJ 07901-1027

EXAMINER

DI NOLA BARON, L

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

10/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/920,159

Applicant(s)

WAGNER ET AL.

Examiner

Liliana Di Nola-Baron

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-35,38,40 and 42-49 is/are rejected.
- 7) ☒ Claim(s) 36,37,39 and 41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 29 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Regarding claims 29 and 34, the phrase "more particularly" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 28 and 30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,294,197. Although the

Art Unit: 1615

conflicting claims are not identical, they are not patentably distinct from each other because both the patent and the instant application are directed to a compressed solid dosage form comprising valsartan and a pharmaceutically acceptable additive. The two sets of claims are largely coextensive.

6. Claims 33, 35, 38 and 40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7, 8, 12 and 13 of U.S. Patent No. 6,294,197. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the patent and the instant application are drawn to a compressed solid dosage form comprising valsartan, HCTZ and a pharmaceutically acceptable additive. The two sets of claims are largely coextensive.

7. Claims 42, 43, 46 and 47 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26 and 52 of U.S. Patent No. 6,294,197. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the patent and the instant application are drawn to a method of treating, comprising administering a compressed solid dosage form comprising valsartan and a pharmaceutically acceptable additive. The two sets of claims are largely coextensive.

8. Claims 44, 45, 48 and 49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 37 and 53 of U.S. Patent No. 6,294,197. Although the conflicting claims are not identical, they are not patentably distinct

Art Unit: 1615

from each other because both the patent and the instant application are drawn to a method of treating, comprising administering a compressed solid dosage form comprising valsartan, HCTZ and a pharmaceutically acceptable additive. The two sets of claims are largely coextensive.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 28, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Gasparo et al.

Applicant's claimed invention refers to a compressed solid dosage form comprising valsartan and an acid as additive.

De Gasparo et al. discloses salts of valsartan, comprising valsartan and hydroxycarboxylic acids, including citric acid (See e.g., p. 2) and teaches that the pharmaceutical compositions of the invention comprise 0.1-100% active ingredient and are manufactured by conventional mixing and granulating (See e.g., p. 4).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include acids in the compositions comprising valsartan, to increase the

Art Unit: 1615

solubility of the preparation. Because of the teachings of De Gasparo et al., that valsartan can be in the form of pharmaceutically acceptable salts, one of ordinary skill in the art would have a reasonable expectation that the dosage form claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Allowable Subject Matter

11. Claims 36, 37, 39 and 41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

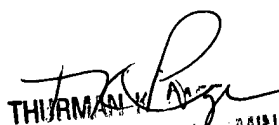
The enclosed reference is cited as related to the field of Applicant's invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

October 24, 2001


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600